PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
5100 WISCONSIN AVENUE, N.W., SUITE 400
WASHINGTON, DC 20016
T: (202) 686-2210 F: (202) 686-2216
PCRM@PCRM.ORG WWW.PCRM.ORG

December 13, 2004

Michael O. Leavitt, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for Sulfanilic acids

Dear Administrator Leavitt:

The following comments on the International Association of Color Manufacturers/HPV Committee (IACM) test plan for sulfanilic acids are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

IACM submitted its test plan on July 9, 2004 for the chemicals Sulfanilic acid and o-Tolulene Sulfonic acid, 4-amino-5-methoxy- (p-Cresidine Sulfonic acid) (CAS RN 121-57-3 and 6471-78-3, respectively). According to the test plan, these chemicals are both intermediates and metabolites of azo dyes, specifically FD&C Yellow 5 and 6, and FD&C Red 40. Consequently, IACM is able to use human and environmental health data from these dyes to fulfill the SIDS endpoints for the Sulfanilic acid category. There are existing and calculated data for the ecotoxicity endpoints of acute fish and aquatic invertebrate toxicity for Sulfanilic acid, as well as data to fulfill the *in vitro* genetic toxicity endpoint. IACM uses these data, in addition to the extensive existing azo dye toxicity data, to propose no additional testing.

Further support for this approach comes from examining metabolism pathways for the azo dyes. In the gastrointestinal tracts of rats, rabbits, and humans, the azo dyes are reduced to sulfonated aromatic amines, including sulfanilic acid and p-cresidine sulfonic acid. The sponsor provides this information both in writing and pictorially.

This test plan is an example of the type of thorough literature research and thoughtful toxicology that is needed to be consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to the HPV program. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org.

Sincerely,

Kristie M Stoick, M.P.H.
Research Analyst

Chad B. Sandusky, Ph.D.
Director of Research